Billing Code 4165-15

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

AGENCY: Health Resources and Services Administration, HHS

ACTION: Notice

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Public Law 104-13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443-1984.

DATES: Comments on this ICR should be received no later than [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or by mail to the HRSA Reports Clearance Officer, 14N39, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443-1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference.

Information Collection Request Title: Countermeasures Injury Compensation Program

OMB No. 0915-0334 – Extension

Abstract: This is an extension request for OMB approval of the information collection requirements for the Countermeasures Injury Compensation Program (CICP or Program). CICP, within the Division of Injury Compensation Programs (DICP), Healthcare Systems Bureau, HRSA, administers the compensation program specified by the Public Readiness and Emergency Preparedness Act of 2005 (PREP Act). CICP provides compensation to eligible individuals who suffer serious injuries directly caused by a covered countermeasure administered or used pursuant to a PREP Act Declaration, or to their estates and/or to certain survivors. A declaration is issued by the Secretary of the Department of Health and Humans Services (Secretary). The purpose of a declaration is to identify a disease, health condition, or a threat to health that is currently, or may in the future constitute, a public health emergency. In addition, the Secretary, through a declaration, may recommend and encourage the development, manufacturing, distribution, dispensing, and administration or use of one or more covered countermeasures to treat, prevent, or diagnose the disease, condition, or threat specified in the declaration. To determine whether a requester is eligible for Program benefits (compensation) for the injury, CICP must review the Request for Benefits Package, which includes the Request for Benefits Form and Authorization for Use or Disclosure of Health Information Form(s), as well as the injured countermeasure recipient's medical records and supporting documentation.

A requester who is an injured countermeasure recipient may be eligible to receive benefits for unreimbursed medical expenses and/or lost employment income. The estate of a deceased countermeasure recipient may also be eligible to receive medical benefits and/or benefits for lost employment income accrued prior to the injured countermeasure recipient's death. If death was the result of the administration or use of the countermeasure, certain survivor(s) of deceased eligible countermeasure recipients may be eligible to receive a death benefit, but not unreimbursed medical expenses or lost employment income benefits. 42 CFR §110.33. The death benefit is calculated using either the "standard calculation" or the "alternative calculation." The "standard calculation" is based on the death benefit available under the Public Safety Officers' Benefits (PSOB) Program. 42 CFR § 110.82(b). The "alternative calculation" is based on the deceased countermeasure recipient's income and is only available to the recipient's dependent(s) younger than age 18 at the time of the countermeasure recipient's death. Continued approval is requested for the required information collection via the Request for Benefits Package (RFB) and for continued use of CICP's mechanisms of medical documentation and supporting documentation collection. During the eligibility review, CICP provides requesters with the opportunity to supplement their Requests for Benefits with additional medical records and supporting documentation before a final Program decision is made. CICP asks requesters to complete and sign a form indicating whether they intend to submit additional documentation prior to the final determination of their case. In addition, approval is requested for the continued use of a benefits documentation package that CICP sends to requesters who may be eligible for compensation, which includes certification forms and instructions outlining the documentation needed to determine the types and amounts of benefits. This documentation

is required under 42 CFR §110.61-110.63 of CICP's implementing regulation to enable the Program to determine the types and amounts of benefits the requester may be eligible to receive. Likely Respondents: Members of the public who believe they have sustained serious physical injuries or deaths as the direct result of the administration or use of a covered countermeasure for a disease, condition, or threat that the Secretary determines either constitutes a current public health emergency, or there is a credible risk that the disease, condition, or threat may in the future constitute such an emergency. Persons who may be eligible to receive benefits from the CICP are:

- (1) Injured countermeasure recipients, as described in § 110.3(n).
- (2) Survivors, as described in §§ 110.3(cc) and 110.11.
- (3) Estates of deceased injured countermeasure recipients, as described in § 110.10(a)(3).

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.

The annual estimate of burden is as follows:

Form Name	Number of Respondents	Number of Responses per Respondent	Total Responses	Average Burden per Response (in hours)	Total Burden Hours
Request for	Respondents	Respondent	Responses	(III Hours)	Tiouis
Benefits Form	100	1	100	11	1,100
and Supporting					
Documentation Documentation					
Authorization					
for Use or	100	1	100	2	200
Disclosure of					
Health					
Information					
Form					
Additional Documentation and Certification	30	1	30	.75	22.5
Benefits					
Package and	30	1	30	.125	3.75
Supporting	30	1	30	.123	3.73
Documentation					
Total	100		100		1,326.25
1.00				Ci. Til 4 1	

^{*}The number 100 represents an estimate of individuals applying for Program benefits. The 4 documents are required of the same 100 individuals or subset of the 100 individuals.

HRSA especially requests comments on: (1) the necessity and utility of the proposed

information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Jason E. Bennett

Director, Division of the Executive Secretariat

[FR Doc. 2016-15710 Filed: 6/30/2016 8:45 am; Publication Date: 7/1/2016]